WYOMING VALLEY
HEALTH CARE SYSTEM

March 31, 2005

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

RE: Reply to a Notice of Violation (License #37-16170-02, Docket #03034844)

To Whom It May Concern:

Pursuant to 10 C.F.R. § 2.201, WVHCS-Hospital ("WVHCS") hereby submits this response to the Notice of Violation letter dated March 1, 2005 from Pamela J. Henderson, Chief, Medical Branch, Division of Nuclear Materials Safety. A response to each of the items requested in the Notice of Violation is set forth below.

(1) Reason for the violation – The Notice of Violation cited WVHCS for a violation of 10 C.F.R. § 35.40, which provides that a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before administration of the gamma stereotactic radiosurgery dose. The documentation error cited in the Notice of Violation resulted from an oversight by the authorized user, which occurred because the authorized user and other WVHCS staff members were focused on the care and treatment of the patient. Specifically, the authorized user encountered difficulties with the position of the head frame that prevented the patient from receiving the appropriate gamma stereotactic radiosurgery dose. The procedure was postponed for a later time, and the authorized user verbally revised the written directive (which was then documented by the physicist). Such revision was not signed and dated in accordance with the requirements set forth in 10 C.F.R.§ 35.40.

(2) Corrective steps taken and results achieved – WVHCS has provided all authorized users, as well as WVHCS physicists and the WVHCS Radiation Safety Officer, with a copy of 10 C.F.R. § 35.40. WVHCS reviewed these requirements and discussed the Notice of Violation with all such persons, and has obtained their written certification that they have reviewed, understand and will comply with the requirements of 10 C.F.R. § 35.40. A copy of the signed certification is attached. Furthermore, WVHCS will conduct both internal and external audits of all gamma knife charts (as described below) to ensure that compliance with these requirements is maintained. To date, WVHCS has not made any revisions to existing written directives since this incident.

(3) Corrective steps taken to avoid further violations – For a period of six months beginning on April 1, 2005, all gamma knife charts will be provided to an outside auditor for review for compliance with relevant Nuclear Regulatory Commission ("NRC") federal regulations, including 10 C.F.R. § 35.40. This outside audit will by conducted by Lawrence S. Chin, M.D., Associate Professor, Department of Neurosurgery, University of Maryland School of Medicine,

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22 S. Greene Street, Suite S-12-D, Baltimore, Maryland 21201-1595. All gamma knife charts also will undergo a weekly chart review as part of an internal audit process beginning in the first week of April 2005. Members of the internal audit team will include a radiation oncologist, a physicist and a registered nurse. The findings from both the external and internal audits will be reported and reviewed at the regular Imaging Services and Radiation Oncology Department quarterly meetings as part of the Department's standard performance improvement process. Minutes of these quarterly meetings will be reviewed by WVHCS' Medical Executive Committee. Results of the internal and external audits also will be presented at the annual meeting of the WVHCS' Quality Council by the Radiation Safety Officer.

(4) Date full compliance will be achieved – April 1, 2005.

WVHCS is confident that the corrective steps set forth in this response letter effectively will enable WVHCS to monitor its compliance with 10 C.F.R. § 35.40 and prevent any further violations.

If you have additional questions, you may contact either one of us at the numbers listed below.

Sincerely,

William R. Host

William R. Host
President and CEO
(570) 552-3006

Cindy Turchin

Cindy Turchin
Radiation Safety Officer
(570) 552-1740

cc: Regional Administrator
U.S. Nuclear Regulatory Commission – Region I
475 Allendale Road
King of Prussia, PA 19406

Robert Hoffman – Vice President
Mary Cummings – General Counsel
Robert Rostock, M.D. – Chairman, Radiation Oncology Department

WYOMING VALLEY HEALTH CARE SYSTEM

CERTIFICATION OF COMPLIANCE WITH 10 C.F.R. § 35.40

Reproduced below is a section of a regulation issued by the Nuclear Regulatory Commission ("NRC"). All authorized users, as well as all WVHCS-Hospital physicists and the WVHCS-Hospital Radiation Safety Officer, must carefully review this NRC regulation, sign the certification at the bottom, and return this page to Cindy Turchin, Director of Imaging Services and Radiation Oncology, by March 30, 2005.

10 C.F.R. § 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.
   (1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information--
   (1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;
   (2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
   (3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
   (4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
   (5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
   (6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
      (i) Before implantation: treatment site, the radionuclide, and dose; and
      (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. (Emphasis added.)
   (1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

I have reviewed, understand and will comply with the requirements of 10 C.F.R. § 35.40.

Robert A Rostock 3-29-5
Robert Rostock, MD — Date

Joseph Krzysik 3.31.05
Joseph Krzysik, MS — Date

3/31/05
Hans Baerwald, MD — Date

Tianyou Xue 3/31/05
Tianyou Xue, PhD — Date

Cindy Turchin 3/29/05
Cindy Turchin, RSO — Date